

REMARKS/ARGUMENTS

In response to the Office Action mailed May 19, 2003, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment. Claims 1 and 8 are amended, Claim 15 was cancelled without prejudice and no claims have been added so that claims 1-14 are currently pending. No new matter has been introduced.

Claims 1-15 were rejected as anticipated by U.S. Patent Number 5,516,781 to Morris et al. (Morris). This rejection is respectfully traversed.

Morris discloses a method for preventing or treating hyperproliferative vascular disease in a mammal by administering an effective amount of an anti-proliferative (rapamycin) alone or in combination with mycophenolic acid. The delivery method may include the use of a stent. Specifically, Morris discloses the use of rapamycin in preventing smooth muscle cell hyperplasia, restenosis and vascular occlusion resulting from mechanically mediated injury. Essentially, Morris discloses treating or preventing hyperproliferative vascular disease in a mammal by administering an anti-proliferative effective amount of rapamycin to the mammal in any number of ways, including a stent. Morris also discloses the combination of rapamycin and mycophenolic acid to treat the same condition.

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The present invention, as claimed in amended independent claim 1, is directed to a method for preventing constrictive remodeling comprising a controlled delivery, by release from a stent, of a compound having anti-proliferative and anti-inflammatory properties in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent. The dosage ranges from about thirty-five micrograms per fifteen to eighteen millimeter stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent. The present invention, as claimed in amended claim 8, is directed to a drug delivery device for treating constrictive vascular remodeling. The device comprises a stent and a therapeutic dosage of an agent having anti-proliferative and anti-inflammatory properties releasably affixed to the stent for the treatment of constrictive vascular remodeling. The agent substantially reducing in-lesion lumen loss both proximal and distal to the stent. The agent is incorporated in a polymeric matrix.

Morris fails to disclose or suggest a stent having anti-proliferative and anti-inflammatory properties in the dose range set forth in the claims. In fact, Morris has no data regarding stent delivery dosages. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application Number 09/850,233, claims 1-15 of, copending Application Number 09/850,507, claims 1-17 of copending Application Number

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09/850,232, claims 1-14 of copending Application Number
09/850,365 and claims 1-15 of copending Application Number
09/575,480.

Applicants understand that these rejections are to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendments to the claims of the present invention and any potential amendments made to the claims of the cited applications, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would like to thank the Examiner for taking the time to conduct a personal interview.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,



Carl J. Evens
Reg. No. 33,874
Attorney for applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518

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